

AN ACT

relating to certain newborn and infant screening and follow-up services.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. The heading to Section 33.0111, Health and Safety Code, is amended to read as follows:

Sec. 33.0111. DISCLOSURE STATEMENT AND CONSENT.

SECTION 2. Section 33.0111, Health and Safety Code, is amended by amending Subsections (a), (b), and (d) and adding Subsections (e), (f), and (g) to read as follows:

(a) The department shall develop a disclosure statement that clearly discloses to the parent, managing conservator, or guardian of a newborn child subjected to screening tests under Section 33.011:

(1) that the department or a laboratory established or approved by the department under Section 33.016 may retain for use by the department or laboratory genetic material used to conduct the newborn screening tests and discloses how the material is managed and used subject to this section and Sections 33.0112 and 33.017; and

(2) that reports, records, and information obtained by the department under this chapter that do not identify a child or the family of a child will not be released for public health research purposes under Section 33.017(c-1) unless a parent,

1 managing conservator, or guardian of the child consents to
2 disclosure; and

3 (3) that newborn screening blood spots and associated
4 data are confidential under law and may only be used as described by
5 Section 33.017 [~~that the parent, managing conservator, or guardian~~
6 ~~may limit the use of the genetic material by providing to the~~
7 ~~department in accordance with Section 33.0112 a written statement~~
8 ~~prohibiting the department or laboratory from retaining the genetic~~
9 ~~material or using the genetic material for any purpose other than~~
10 ~~the conduct of newborn screening tests authorized under this~~
11 ~~chapter].~~

12 (b) The disclosure statement required by Subsection (a)
13 must be included on the form developed by the department to inform
14 parents about newborn screening. The disclosure statement must:

15 (1) [~~be on a separate sheet of the form,~~
16 [~~2)~~] be [~~presented together with the written~~
17 ~~statement described by Subsection (a)(2)] in a format that allows a~~
18 parent, managing conservator, or guardian of a newborn child to
19 consent to disclosure under Section 33.017(c-1) [~~either:~~

20 [~~(A) sign, detach, and mail a portion of the form~~
21 ~~to the department to require the department or laboratory to~~
22 ~~destroy the genetic material on completion of the newborn screening~~
23 ~~tests; or~~

24 [~~(B) check a box and sign next to the box on the~~
25 ~~form a statement indicating the parent, managing conservator, or~~
26 ~~guardian is requiring the department or laboratory to destroy the~~
27 ~~genetic material on completion of the newborn screening tests];~~

1 (2) [~~(3)~~] include instructions on how to complete the
2 portions of the form described by Subdivision (1) [~~Subdivisions~~
3 ~~(2)(A) and (B)~~];

4 (3) [~~(4)~~] include the department's mailing address;
5 and

6 (4) describe how [~~(5) be made available to~~] a parent,
7 managing conservator, or guardian of a newborn child may obtain
8 information regarding consent through alternative sources.

9 (d) The department shall establish procedures for a
10 physician attending a newborn child or the person attending the
11 delivery of a newborn child to provide verification to the
12 department that the physician or person has provided the parent,
13 managing conservator, or guardian of the newborn child the
14 disclosure statement required under this section.

15 (e) The physician attending a newborn child or the person
16 attending the delivery of a newborn child that is not attended by a
17 physician shall submit any document required by the department.

18 (f) This section does not supersede the requirements
19 imposed by Section 33.017.

20 (g) A reference in this section to Section 33.017 means
21 Section 33.017 as added by Chapter 179 (H.B. 1672), Acts of the 81st
22 Legislature, Regular Session, 2009.

23 SECTION 3. Section 33.0112, Health and Safety Code, is
24 amended to read as follows:

25 Sec. 33.0112. DESTRUCTION ~~[STATEMENT~~ PROHIBITING
26 ~~RETENTION]~~ OF GENETIC MATERIAL. (a) The department shall destroy
27 any genetic material obtained from a child under this chapter not

1 later than the second anniversary of the date the department
2 receives the genetic material unless a parent, managing
3 conservator, or guardian of the child consents to disclosure under
4 Section 33.017(c-1) [A parent, managing conservator, or guardian of
5 a newborn child may file with the department a signed written
6 statement prohibiting the department or a laboratory established or
7 approved by the department from retaining any genetic material
8 related to the newborn screening tests conducted under this chapter
9 or using the genetic material for any purpose other than the conduct
10 of the newborn screening tests. A parent, managing conservator, or
11 guardian may file the written statement on a form provided by the
12 department].

13 (b) The department shall destroy any genetic material
14 obtained from a child under this chapter not later than the second
15 anniversary of the date the department receives the genetic
16 material if:

17 (1) a parent, managing conservator, or guardian of the
18 child consents to disclosure under Section 33.017(c-1);

19 (2) the parent, managing conservator, or guardian who
20 consented to the disclosure revokes the consent under Section
21 33.017(i); and

22 (3) the department receives the written revocation of
23 consent under Section 33.017(i) not later than the second
24 anniversary of the date the department received the genetic
25 material [Not later than the 60th day after the department receives
26 the written statement, the department or laboratory shall destroy
27 the genetic material used in the screening tests].

1 (c) The department shall destroy any genetic material
2 obtained from a child under this chapter not later than the 60th day
3 after the date the department receives a written revocation of
4 consent under Section 33.017(i) if:

5 (1) a parent, managing conservator, or guardian of the
6 child consented to disclosure under Section 33.017(c-1);

7 (2) the parent, managing conservator, or guardian who
8 consented to the disclosure or the child revokes the consent under
9 Section 33.017(i); and

10 (3) the department receives the written revocation of
11 consent later than the second anniversary of the date the
12 department received the genetic material [~~An adult individual may~~
13 ~~file with the department a written statement instructing the~~
14 ~~department or a laboratory established or approved by the~~
15 ~~department to destroy any genetic material of the individual that~~
16 ~~is retained and used under this chapter].~~

17 (d) A reference in this section to Section 33.017 means
18 Section 33.017 as added by Chapter 179 (H.B. 1672), Acts of the 81st
19 Legislature, Regular Session, 2009.

20 SECTION 4. Section 33.017, Health and Safety Code, as added
21 by Chapter 179 (H.B. 1672), Acts of the 81st Legislature, Regular
22 Session, 2009, is amended by amending Subsections (a), (b), and (c)
23 and adding Subsections (a-1), (c-1), (e), (f), (g), (h), (i), and
24 (j) to read as follows:

25 (a) In this section:

26 (1) "Affiliated with a health agency" means a person
27 who is an employee or former employee of a health agency.

1 (2) "Commission" means the Health and Human Services
2 Commission.

3 (3) "Commissioner" means the commissioner of state
4 health services.

5 (4) "Health agency" means the commission and the
6 health and human services agencies listed in Section 531.001,
7 Government Code.

8 (5) "Public health purpose" means a purpose that
9 relates to cancer, a birth defect, an infectious disease, a chronic
10 disease, environmental exposure, or newborn screening.

11 (a-1) Reports, records, and information obtained or
12 developed by the department under this chapter are confidential and
13 are not subject to disclosure under Chapter 552, Government Code,
14 are not subject to subpoena, and may not otherwise be released or
15 made public except as provided by this section.

16 (b) Notwithstanding other law, reports, records, and
17 information obtained or developed by the department under this
18 chapter may be disclosed:

19 (1) for purposes of diagnosis or follow-up authorized
20 under Section 33.014;

21 (2) with the consent of each identified individual or
22 an individual authorized to consent on behalf of an identified
23 child;

24 (3) as authorized by court order;

25 (4) to a medical examiner authorized to conduct an
26 autopsy on a child or an inquest on the death of a child; ~~[or]~~

27 (5) to public health programs of the department for

1 public health research purposes, provided that the disclosure is
2 approved by:

3 (A) the commissioner or the commissioner's
4 designee; and

5 (B) an institutional review board or privacy
6 board of the department as authorized by the federal privacy
7 requirements adopted under the Health Insurance Portability and
8 Accountability Act of 1996 (Pub. L. No. 104-191) contained in 45
9 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E;

10 (6) for purposes relating to review or quality
11 assurance of the department's newborn screening under this chapter
12 or the department's newborn screening program services under
13 Subchapter C, provided that no disclosure occurs outside of the
14 department's newborn screening program;

15 (7) for purposes related to obtaining or maintaining
16 federal certification, including related quality assurance, for
17 the department's laboratory, provided that no disclosure occurs
18 outside of the department's newborn screening program; or

19 (8) for purposes relating to improvement of the
20 department's newborn screening under this chapter or the
21 department's newborn screening program services under Subchapter
22 C, provided that the disclosure is approved by the commissioner or
23 the commissioner's designee.

24 (c) Notwithstanding other law, reports, records, and
25 information that do not identify a child or the family of a child
26 may be released without consent if the disclosure is for:

27 (1) statistical purposes;

1 (2) purposes related to obtaining or maintaining
2 federal certification, including related review and [approval, or]
3 quality assurance:

4 (A) for the department's laboratory that require
5 disclosure outside of the department's newborn screening program;
6 or

7 (B) for a public or private laboratory to perform
8 newborn screening tests that are not part of inter-laboratory
9 exchanges required for federal certification of the department's
10 laboratory, provided that the disclosure is approved by the
11 commissioner or the commissioner's designee; or

12 (3) other [~~purposes relating to review, quality~~
13 ~~assurance, or improvement of the department's newborn screening~~
14 ~~under this chapter or the department's newborn screening program~~
15 ~~services under Subchapter C,~~

16 [~~(4) research purposes, provided that the disclosure~~
17 ~~is approved by an institutional review board or privacy board of the~~
18 ~~department; or~~

19 [(5)] quality assurance purposes related to public
20 health testing equipment and supplies, provided that the disclosure
21 is approved by:

22 (A) the commissioner or the commissioner's
23 designee [~~assessment is performed by a person who is not a~~
24 ~~laboratory]; and~~

25 (B) [~~only newborn screening specimens are~~
26 ~~disclosed; and~~

27 [~~(C) the disclosure is approved by] an~~

1 institutional review board or privacy board of the department.

2 (c-1) Notwithstanding other law, reports, records, and
3 information that do not identify a child or the family of a child
4 may be released for public health research purposes not described
5 by Subsection (b)(5) if:

6 (1) a parent, managing conservator, or guardian of the
7 child consents to the disclosure; and

8 (2) the disclosure is approved by:

9 (A) an institutional review board or privacy
10 board of the department; and

11 (B) the commissioner or the commissioner's
12 designee.

13 (e) If disclosure is approved by the commissioner or the
14 commissioner's designee under Subsection (c)(3) or (c-1), the
15 department shall post notice on the newborn screening web page on
16 the department's Internet website that disclosure has been
17 approved. The commissioner shall determine the form and content of
18 the notice.

19 (f) In accordance with this section, the commissioner or the
20 commissioner's designee:

21 (1) may approve disclosure of reports, records, or
22 information obtained or developed under this chapter only for a
23 public health purpose; and

24 (2) may not approve disclosure of reports, records, or
25 information obtained or developed under this chapter for purposes
26 related to forensic science or health insurance underwriting.

27 (g) An institutional review board or privacy board of the

1 department that reviews a potential disclosure under this section
2 must include at least three persons who are not affiliated with a
3 health agency, one of whom must be a member of the public.

4 (h) Nothing in this section affects the requirement that
5 screening tests be performed under Section 33.011.

6 (i) If a parent, managing conservator, or guardian of a
7 child consents to disclosure under this section:

8 (1) the parent, managing conservator, or guardian who
9 consented to the disclosure may revoke the consent, in writing, at
10 any time by using a form designated by the department; and

11 (2) the child may revoke the consent, in writing, at
12 any time on or after the date the child attains the age of majority
13 by using a form designated by the department.

14 (j) If a person revokes consent under Subsection (i), the
15 department shall destroy any genetic material obtained from the
16 child as provided by Section 33.0112.

17 SECTION 5. Section 47.001(2), Health and Safety Code, is
18 amended to read as follows:

19 (2) "Birthing facility" means:

20 (A) a hospital licensed under Chapter 241 that
21 offers obstetrical services [~~and is located in a county with a~~
22 ~~population of more than 50,000~~]; [~~or~~]

23 (B) a birthing center licensed under Chapter 244;

24 (C) a children's hospital; or

25 (D) a facility, maintained or operated by this
26 state or an agency of this state, that provides obstetrical
27 services [~~that is located in a county with a population of more than~~

1 ~~50,000 and that has 100 or more births per year].~~

2 SECTION 6. Section 47.003, Health and Safety Code, is
3 amended by amending Subsections (a), (c), (d), and (e) and adding
4 Subsections (a-1) and (f) to read as follows:

5 (a) A birthing facility, through a program certified by the
6 department under Section 47.004, shall perform, either directly or
7 through a transfer agreement, ~~[offer the parents of a newborn]~~ a
8 hearing screening ~~[for the newborn]~~ for the identification of
9 hearing loss on each newborn or infant born at the facility before
10 the newborn or infant is discharged from the facility unless:

11 (1) the parent declines the screening;

12 (2) the newborn or infant is transferred to another
13 facility before the screening is performed; or

14 (3) the screening has previously been completed.

15 (a-1) The birthing facility ~~[screening]~~ shall inform the
16 parents ~~[be offered]~~ during ~~[the birth]~~ admission that:

17 (1) the facility is required by law to screen a newborn
18 or infant for hearing loss; and

19 (2) the parents may decline the screening ~~[, and the~~
20 ~~parents shall be informed that information may be provided to the~~
21 ~~department upon their written consent].~~

22 (c) Subject to Section 47.008, the ~~[The]~~ department shall
23 ~~[may]~~ maintain data and information on each newborn or infant who
24 receives a hearing screening under Subsection (a) ~~[services under a~~
25 ~~program].~~

26 (d) The department shall ensure that intervention is
27 available to families for a newborn or infant identified as having

1 hearing loss and that the intervention is managed by state programs
2 operating under the Individuals with Disabilities Education Act (20
3 U.S.C. Section 1400 et seq.).

4 (e) The department shall ensure that the intervention
5 described by Subsection (d) is available for a newborn or infant
6 identified as having hearing loss not later than the sixth month
7 after the newborn's or infant's birth and through the time the child
8 is an infant unless the infant has been hospitalized since birth.

9 (f) If a newborn or an infant receives medical intervention
10 services, including a hearing aid or cochlear implant, the
11 intervention specialist shall report the results of the
12 intervention to the department.

13 SECTION 7. Chapter 47, Health and Safety Code, is amended by
14 adding Section 47.0031 to read as follows:

15 Sec. 47.0031. FOLLOW-UP SCREENING. (a) The program that
16 performed the hearing screening under Section 47.003 shall provide
17 the newborn's or infant's parents with the screening results. A
18 birthing facility, through the program, shall offer a follow-up
19 hearing screening to the parents of a newborn or infant who does not
20 pass the screening, or refer the parents to another program for the
21 follow-up hearing screening. The follow-up hearing screening
22 should be performed not later than the 30th day after the date the
23 newborn or infant is discharged from the facility.

24 (b) If a newborn or an infant does not pass the screening in
25 a follow-up hearing screening, the program that performed the
26 follow-up hearing screening on the newborn or infant shall:

27 (1) provide the newborn's or infant's parents with the

1 screening results;

2 (2) assist in scheduling a diagnostic audiological
3 evaluation for the newborn or infant, consistent with the most
4 current guidelines in the Joint Committee on Infant Hearing
5 Position Statement, or refer the newborn or infant to a licensed
6 audiologist who provides diagnostic audiological evaluations for
7 newborns or infants that are consistent with the most current
8 guidelines in the Joint Committee on Infant Hearing Position
9 Statement; and

10 (3) refer the newborn or infant to early childhood
11 intervention services.

12 SECTION 8. Sections 47.004(b) and (d), Health and Safety
13 Code, are amended to read as follows:

14 (b) In order to be certified, the program must:

15 (1) provide hearing screening using equipment
16 recommended by the department;

17 (2) use appropriate staff to provide the screening;

18 (3) maintain and report data electronically as
19 required by the department;

20 (4) distribute family, health care provider, and
21 physician educational materials standardized by the department;

22 [~~and~~]

23 (5) provide information, as recommended by the
24 department, to the parents on follow-up services for newborns and
25 infants who do not pass the [~~with abnormal~~] screening; and

26 (6) be supervised by:

27 (A) a physician;

1 (B) an audiologist;

2 (C) a registered nurse; or

3 (D) a physician assistant ~~[results]~~.

4 (d) The department may renew the certification of a program
5 on a periodic basis as established by board rule in order to ensure
6 quality services to newborns, infants, and families.

7 SECTION 9. Section 47.005, Health and Safety Code, is
8 amended by amending Subsections (a) and (b) and adding Subsections
9 (d) and (e) to read as follows:

10 (a) A birthing facility that operates a program shall
11 distribute to the parents of each newborn or infant who is screened
12 educational materials that are standardized by the department
13 regarding screening results and follow-up care.

14 (b) A birthing facility that operates a program shall report
15 screening results to:

16 (1) the parents;

17 (2) [] the newborn's or infant's attending
18 physician, primary care physician, or other applicable health care
19 provider; ~~[]~~ and

20 (3) the department.

21 (d) The department may coordinate the diagnostic
22 audiological evaluation required under Section 47.0031(b)(2). A
23 diagnostic audiological evaluation must be completed on the newborn
24 or infant:

25 (1) not later than the third month after the newborn's
26 or infant's birth unless the newborn or infant has been
27 hospitalized since birth; or

1 (2) upon referral by the newborn's or infant's primary
2 care physician or other applicable health care provider.

3 (e) An audiologist who performs a diagnostic audiological
4 evaluation under this chapter shall report the results of the
5 evaluation to:

6 (1) the parents;

7 (2) the newborn's or infant's primary care physician
8 or other applicable health care provider; and

9 (3) the department under Section 47.007(b).

10 SECTION 10. Section 47.007, Health and Safety Code, is
11 amended by amending Subsection (b) and adding Subsections (d)
12 through (h) to read as follows:

13 (b) Subject to Section 47.008, a [A] qualified hearing
14 screening provider, hospital, health care provider, physician,
15 audiologist, or intervention specialist shall [may] access the
16 information management, reporting, and tracking system to provide
17 information[~~, where available,~~] to the department and may obtain
18 information from the department[~~, including information]~~ relating
19 to:

20 (1) the results of each hearing screening performed
21 under Section 47.003(a) or 47.0031(a);

22 (2) the results of each diagnostic audiological
23 evaluation required under Section 47.0031(b)(2);

24 (3) [~~1~~] infants who receive follow-up care;

25 (4) [~~2~~] infants identified with hearing loss;

26 (5) [~~3~~] infants who are referred for intervention
27 services; and

1 (6) [~~4~~] case level information necessary to report
2 required statistics to:

3 (A) the Maternal and Child Health Bureau on an
4 annual basis; and

5 (B) the federal Centers for Disease Control and
6 Prevention.

7 (d) A birthing facility described by Subsection (a) shall
8 report the resulting information in the format and within the time
9 frame specified by the department.

10 (e) A qualified hearing screening provider, audiologist,
11 intervention specialist, educator, or other person who receives a
12 referral from a program under this chapter shall:

13 (1) provide the services needed by the newborn or
14 infant or refer the newborn or infant to a person who provides the
15 services needed by the newborn or infant; and

16 (2) provide, with the consent of the newborn's or
17 infant's parent, the following information to the department or the
18 department's designee:

19 (A) results of follow-up care;

20 (B) results of audiologic testing of an infant
21 identified with hearing loss; and

22 (C) reports on the initiation of intervention
23 services.

24 (f) A qualified hearing screening provider, audiologist,
25 intervention specialist, educator, or other person who provides
26 services to an infant who is diagnosed with hearing loss shall
27 provide, with the consent of the infant's parent, the following

1 information to the department or the department's designee:

2 (1) results of follow-up care;

3 (2) results of audiologic testing; and

4 (3) reports on the initiation of intervention
5 services.

6 (g) A hospital that provides services under this chapter
7 shall use the information management, reporting, and tracking
8 system described by this section, access to which has been provided
9 to the hospital by the department, to report, with the consent of
10 the infant's parent, the following information to the department or
11 the department's designee:

12 (1) results of all follow-up services for an infant
13 who does not pass the screening described by Section 47.003(a) if
14 the hospital provides the follow-up services; or

15 (2) the name of the provider or facility to which the
16 hospital refers an infant who does not pass the screening described
17 by Section 47.003(a) for follow-up services.

18 (h) Subject to Section 47.008, a qualified hearing
19 screening provider, hospital, health care provider, physician,
20 audiologist, or intervention specialist may obtain information
21 from the department relating to:

22 (1) the results of each hearing screening performed
23 under Section 47.003(a) or 47.0031(a);

24 (2) the results of each diagnostic audiological
25 evaluation required under Section 47.0031(b)(2);

26 (3) infants who receive follow-up care;

27 (4) infants identified with hearing loss; and

1 (5) infants who are referred for intervention
2 services.

3 SECTION 11. Chapter 47, Health and Safety Code, is amended
4 by adding Sections 47.010 and 47.011 to read as follows:

5 Sec. 47.010. RULEMAKING. (a) The executive commissioner
6 of the Health and Human Services Commission may adopt rules for the
7 department to implement this chapter.

8 (b) If the executive commissioner adopts rules, the
9 executive commissioner shall consider the most current guidelines
10 established by the Joint Committee on Infant Hearing.

11 Sec. 47.011. DUTIES OF MIDWIFE. (a) In this section,
12 "midwife" has the meaning assigned by Section 203.002, Occupations
13 Code, and includes a nurse midwife described by Section 301.152,
14 Occupations Code.

15 (b) A midwife who attends the birth of a newborn:

16 (1) is not required to offer the parents of the newborn
17 a hearing screening for the newborn for the identification of
18 hearing loss; and

19 (2) shall refer the parents of the newborn to a
20 birthing facility or a provider that participates in the program
21 and make a record of the referral.

22 SECTION 12. Section 47.002, Health and Safety Code, is
23 repealed.

24 SECTION 13. (a) Not later than January 1, 2012, the
25 executive commissioner of the Health and Human Services Commission
26 shall prescribe a form to document a parent's decision to decline
27 screening under Section 47.003(a)(1), Health and Safety Code, as

1 added by this Act, in consultation with persons and organizations
2 interested in newborn hearing screening.

3 (b) The Department of State Health Services may post the
4 form prescribed under Subsection (a) of this section on the
5 department's Internet website.

6 (c) A person or facility is not required to comply with the
7 changes in law made by this Act to Chapter 47, Health and Safety
8 Code, until January 1, 2012.

9 SECTION 14. (a) Except as provided by Subsection (b) of
10 this section, this Act takes effect immediately if it receives a
11 vote of two-thirds of all the members elected to each house, as
12 provided by Section 39, Article III, Texas Constitution. If this
13 Act does not receive the vote necessary for immediate effect, this
14 Act takes effect September 1, 2011.

15 (b) The changes made to Sections 33.0111 and 33.0112, Health
16 and Safety Code, as amended by this Act, and Section 33.017(c-1), as
17 added by this Act, take effect June 1, 2012.

President of the Senate

Speaker of the House

I certify that H.B. No. 411 was passed by the House on April 11, 2011, by the following vote: Yeas 147, Nays 0, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 411 on May 27, 2011, by the following vote: Yeas 134, Nays 4, 2 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 411 was passed by the Senate, with amendments, on May 23, 2011, by the following vote: Yeas 29, Nays 1.

Secretary of the Senate

APPROVED: _____

Date

Governor